

REMARKS

Status of the Claims

Claims 1-59 were pending. Pursuant to a restriction requirement, claims 43, 44 and 53-58 have been withdrawn from consideration. Examined claims 1-42, 45-52 and 58-59 were variously rejected under 35 U.S.C. §§ 102, 103 and 112, second paragraph.

Applicants note that claims 19-22, 24-46 and 59 were not rejected under §§ 102 or 103 and are therefore considered free of the cited art.

Claim 1 has been amended herein solely to clarify that the transposon cassette expresses at least one light generating polypeptide sequence. *See*, original claim 4. Accordingly, claim 4 has been canceled and the dependencies of claims 5, 6 14 and 18 have been corrected. In addition, claim 46 has been amended to no longer depend from a withdrawn claim. Thus, claims 1-3, and 5-59 are pending as shown above.

Election/Restriction

Applicants appreciate the distinction between the dictionary definitions of "overlapping" and "commensurate." However, neither term is relevant to Restriction/Election practice. Rather, as set forth in M.P.E.P. § 803, the relevant inquiry is whether searching the allegedly distinct inventions together would result in a serious burden to the Examiner:

For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant.

Thus, the assertion that the allegedly distinct inventions of each group must be "commensurate" in scope in order for a search not be a serious burden is in error. In the pending case, Applicants again submit that the lack of serious burden on the Examiner is clearly demonstrated by the Office's own classification of ALL allegedly distinct inventions in the same class (class 435). Therefore, the Examiner has failed to make a *prima facie* case that searching the groups together would be burdensome. Indeed, the Examiner's own classification of all groups in class 435 is clear evidence that it is not a serious burden to examiner all claims together.

Furthermore, Applicants expressly reverse their right to rejoinder of method claims in Groups II-VI as well as their right under 35 USC § 121 to file one or more continuing

applications during the pendency of this application.

Accordingly, Applicants again submit that the six-way Restriction Requirement should be withdrawn and claims 1-59 should be examined together.

Claim Objections

Claim 46 was objected to as depending from a withdrawn claim and correction of the dependency was required. For the reasons noted above, Applicants submit that the claims should all be examined in a single group and, accordingly, amendment should not be required. Nonetheless, in a sincere effort to advance prosecution, claim 46 has been amended as requested. Therefore, the objection has been obviated.

35 U.S.C. § 112, Second Paragraph

Claims 1-42, 45-52, 58 and 59 were rejected as allegedly indefinite. (Office Action, pages 3-4). Specifically, claims 1 and 21 (and claims depending therefrom) were alleged to be indefinite for reciting the term "derived from a transposon." *Id.* It is maintained that it is unclear "what steps constitute the derivation of the transposon sequence or how much derivation (i.e. mutation of the sequence) is required for the transposon to be considered 'derived.'" *Id.*

For the reasons of record, Applicants again submit that the term "derived from a transposon" is not indefinite. Nonetheless, in a sincere effort to advance prosecution, the term has been removed from the claims, thereby obviating this rejection. It is to be understood that the claims encompass sequences having sequences identical to wild type sequences as well as those sequences that do not exist in nature.

35 U.S.C. § 102(b)

Claims 1-3, 13, 23 and 47-49 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Knudtson et al. (1993) *Gene* 137:217-222 (hereinafter "Knudtson"). (Final Office Action, pages 4-7). In brief, it is maintained that Knudtson teaches the transposon cassettes as claimed and that the "functional" characteristics regarding the use of these cassettes in gram-positive bacteria is irrelevant to the anticipation inquiry. *Id.* Accordingly, the distinction between Knudtson's cassettes, which are designed for use in mycoplasma, and the claimed cassettes, which are designed for use in gram-positive bacteria was deemed irrelevant. *Id.*

Because functional limitations cannot be ignored, Applicants traverse the rejection and supporting remarks.

It is well settled that functional limitations of a claim, be it a composition or a method claim, cannot be ignored when determining patentability. *See, e.g., Hybritech v. Monoclonal*

Antibodies, 231 USPQ 81 (Fed. Cir. 1986); M.P.E.P § 2173.05(g) Functional Limitations, Eighth Edition. Thus, it was and remains entirely relevant that claims 1-3, 13, 23 and 47-49 all require that the transposon be capable of promoting transcription in gram-positive organisms. Nowhere does Knudtson teach or suggest such a functional limitation.

Moreover, the claims have been amended as shown above to incorporate the limitations of previous claim 4, namely that the cassettes are capable of expressing at least one light generating polypeptide sequence in gram positive bacteria. As already acknowledged by the Office, Knudtson does not describe or demonstrate such cassettes and, accordingly, cannot anticipate any of the pending claims. Withdrawal of this rejection is in order.

35 U.S.C. § 103

Claims 4-12, 14-18, 50-52 and 58 were rejected under 35 U.S.C. § 103 as allegedly obvious over Knudtson in combination with one or more secondary references. In particular, claims 4, 5, 14, 15, 50-52 and 58 were rejected as allegedly obvious over Knudtson in view of U.S. Patent No. 6,100,661 (hereinafter "Lajoie"). Claims 6-10 and 16 were rejected as allegedly obvious over Knudtson in view of Lajoie and in further view of Jacobs et al. (1991) *Mol. Gen. Genet* 230:251-256 (hereinafter "Jacobs"). Claims 11 and 12 were rejected as allegedly unpatentable over Knudtson in view of Lajoie in further view of Jacobs and in further view of Baldwin et al. (1990) *Biochem.* 29:5509-5515 (hereinafter "Baldwin"). Claims 17, 18 and 58 were rejected as allegedly unpatentable over Knudtson in view of Lajoie in further view of Jacobs and in further view of U.S. Patent No. 5,591,601 (hereinafter "Wagner").

Knudtson is cited as above. Lajoie is cited as before for allegedly teaching the construction of transposon cassettes containing a promoterless luciferase encoding gene "used in effectively the same manner as Knudtson." (Final Office Action, page 7). It is alleged that it would have been obvious to substitute luciferase for lacZ in Knudtson's cassettes. *Id.* Jacobs is cited for teaching the use of a ribosome binding sequence from gram-positive bacteria in front of the marker gene. (Final Office Action, page 8). Baldwin is cited for teaching identification of a yellow fluorescent protein. (Final Office Action, page 8). Finally, Wagner is cited for disclosing kanamycin resistance gene. (Final Office Action, page 8).

Should the rejections under 35 U.S.C. § 103 be maintained despite the foregoing claim amendments, Applicant reiterates the fact that there is no teaching, suggestion or motivation within the cited references to support the rejection made by the Examiner.

The Examiner bears the burden of establishing a *prima facie* case of obviousness. *See, e.g., In re Ryckaert*, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); and *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The reference must teach all the limitations of the claimed

invention and, moreover, suggests the desirability of arriving at the claimed subject matter. (*See, e.g., Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991) stating that "hindsight is not a justifiable basis on which to find that the ultimate achievement of along sought and difficult scientific goal was obvious" and *In re Laskowski*, 10 USPQ2d 1397, 1399 (Fed. Cir. 1989) stating that "the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.")

Pending claim 5-12, 14-18, 50-52 and 58 are all directed to transposon cassettes that (i) lack control sequences that are capable of promoting transcription in the target organism (referred to hereinafter as "promoterless") and, in addition, (ii) are capable of expressing a light generating polypeptide in gram-positive bacteria.

Nowhere do any of the references teach or suggest the desirability of the claimed promoterless transposon cassettes expressing at least one light generating protein in gram-positive organisms. Nor is there any motivation in any of the references to combine them as set forth in the Office Action.

As noted above, there is nothing in Knudtson suggesting a transposon as claimed. In particular, Knudtson is entirely silent as to both light generating proteins and gram-positive bacteria. Lajoie is also silent as gram-positive bacteria and, indeed, the only bioreporter bacteria described in this reference is the gram-negative cocci belonging to the genus *Pseudomonas*. *See, e.g.*, col. 15, lines 15-23 of Lajoie. Thus, there is no motivation to combine Knudtson and Lajoie as set forth by the Office and, moreover, no combination that would lead one of skill in the art to the claimed subject matter.

Jacobs, the only reference that mentions gram-positive bacteria, fails to provide any description of transposon cassettes comprising promoterless internal nucleotide sequences. In fact, Jacobs is premised on the notion that a powerful promoter (Pxyn) must be coupled to the luciferase-encoding sequence in order to get expression in gram-positive organisms. How can there be any motivation to combine Jacobs with Knudtson and/or Lajoie when the cassettes in Jacobs necessarily and in all cases contain a promoter?

For their parts, Wagner and Baldwin do not teach or suggest expression of sequences contained on transposon cassettes in gram-positive bacteria.

Furthermore, in maintaining this rejection, the Examiner has again improperly ignored the requirement that the claimed compositions are capable of expressing a light generating protein in gram-positive organisms. A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. (M.P.E.P. 2173.05(g) Functional Limitations,

Eighth Edition). There is nothing inherently wrong with defining some part of an invention in functional terms and functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). Indeed, where the particular intended result (in this case, expression of a light generating protein in gram-positive bacteria) is a limitation of the pending claims it is entirely relevant to patentability. Accordingly, the requirement in these claims regarding the target organism is entirely relevant the obviousness inquiry and establishes, along with the other evidence of record, that the claims are patentable over any combination of the cited references.

Here, the pending claims expressly recite that the claimed promoterless transposon cassettes express at least one light generating protein in a gram-positive bacteria and, hence, these limitations are relevant to patentability. It is unacceptable for the Examiner to ignore any of these limitations and assert that any art related to transposon cassettes is relevant, much less than these references render the particularly claimed invention unpatentable. Likewise, the Examiner cannot ignore the legal axiom that obviousness cannot be based on what was allegedly inherent. When the proper legal standards of obviousness are applied, it is clear that the claimed compositions, drawn to promoterless transposon cassettes that express light generating polypeptide sequence(s), are in no way obvious over the cited references.

There is, in sum, no motivation provided by the cited references to arrive at transposon cassettes as recited in the pending claims. The elements of the claimed transposon cassettes are precisely defined -- in the claims themselves, not in the references. None of the references teach that promoterless transposon cassettes comprising a sequence encoding a light generating protein would be capable expressing that light generating protein in gram-positive bacteria. Therefore, in order to bring prosecution to a speedy conclusion, Applicants submit that the remaining rejections under Section 103 be withdrawn and the claims indicated as allowable.

CONCLUSION

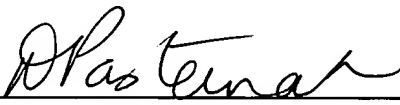
Applicants believe that the claimed subject matter is now in condition for allowance and early notification to that effect is respectfully requested. If any issues remain to be addressed, the Examiner is encouraged to telephone the undersigned.

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